Amendment #1
to RFP-NIH-NIAID-DMID-03-33
"DMID Clinical Trials Management"

Amendment to Solicitation No.:	NIH-NIAID-DMID-03-33
Amendment No.:	1 (2nd posting)
Amendment Date:	November 27, 2002 (Questions 1-19) **December 20, 2002 (Questions 20-30)**
RFP Issue Date:	October 10, 2002
Proposal Due Date:	January 7, 2003, at 4:00 P.M. local time
Issued By:	Jacqueline C. Holden Senior Contracting Officer NIH/NIAID Contract Management Branch 6700 B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Joshua LaVine, Contract Specialist; JL276z@nih.gov Nancy Hershey, Contracting Officer; nh11x@nih.gov
Name and Address of Offeror:	To All Potential Offerors

THIS AMENDMENT PROVIDES QUESTIONS SUBMITTED BY OFFERORS AND THE RESPONSES PROVIDED BY THE NIAID PROJECT OFFICER. ANY FURTHER QUESTIONS AND THEIR RELATED RESPONSES WILL BE ADDED TO THIS AMENDMENT UPON RECEIPT. ALL OFFERORS SHOULD REFER BACK TO THIS AMENDMENT. ALL OFFERORS SHOULD REFER BACK TO THIS (AMENDMENT #1) FOR FUTURE QUESTIONS AND RESPONSES.

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS NOT** been extended. Offerors must acknowledge receipt of this amendment. Failure to receive your acknowledgement of this amendment may result in the rejection of your offer. This amendment shall be acknowledged in the following manner:

AMENDMENT #1 – FORM VERSION DATE: DECEMBER 20, 2002:

AMENDMENT PURPOSE:

(1) To provide additional questions and responses to this RFP, questions 20 through 30; and to revise the answer to Question #9 in Amendment #1, dated November 27, 2002 and; to delete the proposal intent sheet, which was due on December 6, 2002.

2). Revise the Page Limits on page 25 of the RFP provided below.

Page Limits – THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 150 PAGES [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters or Intent, etc but excluding Case Report Forms and Monitoring SOPs]. ANY PROPORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

> **Note that although no page limit has been placed on the Business Proposal, Offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.**

3.) The following provision applies to this solicitation and is hereby incorporated into Section L under item 2.a. (General Instructions):

- Guidance Regarding Federal Government Collaborations

In keeping with FAR 3.6 and recent legal decisions involving conflict of interest issues, it is the policy of the NIAID that any proposal either submitted by a Federal agency or submitted by an Offeror that includes the collaboration of a Federal agency or Federal employee must include a letter describing the role and effort being provided by that government agency and/or employee and stating that: (1) no actual or appearance of a conflict of interest exists with the proposed effort; and (2) the collaborator's supervisor is aware of and approves of the effort. This letter **must** be signed by both the designated agency ethics official (DAEO) and the head of the agency (or his/her designate). The NIAID reserves the right to reject a proposal that includes effort by Federal government employees in order to avoid any actual or appearance of a conflict of interest.

4.) Questions and Answers follow:

Question 1: Is the separate data coordinating center contract an open competition? If so, where do I find the RFP?

Answer 1: It's an existing contract.

Question 2: Could you clarify whether there will be any clinical data collection and management activity (other than the DMID's Pharmacovigilance Program), and, if so, how much?

Answer 2: This is not a data coordinating center contract. DMID has a separate contract for that function for clinical trials.

Question 3: Will there be a meeting to discuss general issues related to the application in response to RFP for DMID-03-33?

Answer 3: This is not planned.

Question 4: Will the successful applicant have responsibility only for new applications considered relevant for Biodefense or will there be responsibilities for any of the 130 ongoing trials?

Answer 4: Successful offerors will be responsible for new and ongoing trials.
.

Question 5: Can you give any guidance about the type of trials by "offending agent"? Should we assume that the trial could involve any type of potential threat or that the major (only) focus should be on microbes. Further, if only microbes, should we assume that trials will involve both treatment (eg.antibiotics) or preventive (eg. vaccines) modalities? If not solely on microbes, what other threats have been included (toxins, chemicals, radiation)?

Answer 5: Vaccines, Drugs and other Biologicals e.g. Monoclonal Antibodies.

Question 6: What involvement, if any, will the successful applicant have in the selection, design, data management, statistical analysis or publication of results of the trials?

Answer 6: We have a separate data coordinating center contract which does interact in the types of activities described in this question. The RFP focuses on support for clinical trials – not design and data analysis.

Question 7: If proposals are due on January 7, when will the successful offerors be notified?

Answer 7: The proposals with be reviewed by a peer review. Offerors should be notified of their inclusion or exclusion of the competitive range sometime in May 2003.

Question 8: The Proposal Intent Response Sheet is due before November 29, 2002. Must offerors receive an approval for submission based upon this sheet and if so, when?

Answer 8: The information received on the Proposal Intent Response sheet is used to provide offerors with instructions and login codes, passwords for electronic proposal submission.

Question 9: Size Standard is 500 employees. Does a company have to have at least 500 employees to bid on this proposal?

Answer 9: **The answer to Question #9 dated November 27, 2002, was incorrect. This is not a Small Business Set-Aside. The NAICS code is FYI. There are no limits on size standards. Please see Section L., Paragraph b.**

Question 10: Does existing data need to be migrated to the new databases being developed? If yes, is the data to be migrated, in one location or dispersed across several locations? In what system (application) is the data currently being maintained?

Answer 10: Yes, in some cases. In the instances where the NIAID has existing systems, the data is dispersed across several locations and is maintained in various forms, including paper (e.g., safety reporting – SOW item D.12) and electronic MS Word and Excel files (e.g., clinical monitoring data). During the performance of the contract it is anticipated that new databases will need (e.g., clinical trial metrics/performance, training) to be developed. For more information about NIAID's electronic capacities see Communications Management note contained on page 58 of the RFP.

Question 11: Are only Commercial Off The Shelf (COTS) products to be used in providing the activities outlined in Section F - Information Management Activities?

Answer 11: Yes. Refer to item F.1

Question 12: Is the Government expecting the contractor to recommend specific COTS products for Section F - Information Management Activities, or is it expecting a general approach and methodology for addressing the requirements?

Answer 12: This is up to the offeror. Offerors are advised to provide its best approach to address the Government's needs.

Question 13: What are the NIAID standards that COTS products must be compatible with?

Answer 13: For more information about NIAID's electronic capacities see Communications Management note contained on page 58 of the RFP.

Question 14: Does NIAID, DMID have an existing safety database? If so, what is the current software application? Will data need to be migrated into the newly designed database as part of the proposed work?

Answer 14: No. NIAID's current system is based on paper, as described in SOW, Item D.12 – page 11.

Question 15: Do the estimated 2 day site initiation and assessment visits and the 4 day follow-up (monitoring) visits include travel time to and from the site, and does it allow for two or four actual days on site for each site?

Answer 15: No. Travel time is not included in these estimates.

Question 16: Under 2a(1) the contractor will assist DMID clinical investigators in the design, development, writing and review, including the collection and synthesizing of review comments, of protocols and protocol amendments, risk information, Investigator Brochure updates, study manuals of procedures, source documentation guidelines, study specific procedures, case report forms, and informed consent forms. Under 2a(2) the contractor develops and use DMID-approved standardized protocol and associated document templates, when appropriate.

The DMID website lists a protocol checklist, IRB guidance, SAE reporting guidelines, etc.; however, there is no active link to these documents. Can access to these and any existing procedural manuals be made available?

Answer 16: Protocol format and SAE reporting are consistent with ICH guidelines for GCP as well as CFR 21, Part 312. IRB guidance can be found in 45CFR Part 46.

A standardized monitoring report form utilized by DMID (see page 58, note 9 RFP.) is included below.

Question 17: Which countries will most likely participate in this clinical research program? Please provide a breakdown of number of investigational sites in US, Asia, Africa, South America, and Europe.

Answer 17: The location of future trials is unknown at this time. Information on the locations of current DMID sponsored trials is available on the NIAID website. Also, refer to page 58, item d.6., of the RFP for added information.

Question 18: Will both local and central laboratories be used in this clinical research program? If so, has a central laboratory already been established? Which services are provided by the central laboratory? Which services are expected from local laboratories?

Answer 18: The laboratory location(s) and services are dependent on the individual trial/study requirements and will be determined at the onset of each trial/study. DMID has not established a central laboratory to support its sponsored studies.

Question 19: Is the proposed centralized web-based database management system expected to collect per subject data or hold cumulative tracking data (clinical metrics) for study progress and status evaluation?

Answer 19: The answer is both. We're asking that multiple databases be developed (see Item F.1.). The clinical trials metrics database (item F.1.c.) would most likely include more general trial/study (by site) information, while the database for the adverse events would typically include more specific individual study subject data.

DMID CLINICAL TRIAL MONITORING REPORT
SUMMARY OF DMID STUDY INTERIM VISIT REPORT

VISIT DATE (S)		**ISSUE DATE**	
STUDY SITE			
PI NAME			
CLINICAL SITE MONITOR			
CLINICAL TRIAL			
IND #		**DMID PROTOCOL #**	

TYPE OF STUDY:

☐ Drug ☐ Vaccine ☐ Challenge ☐ Other _____
☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Other _____
☐ Single Center ☐ Multi-center

Test Article name(s):
Date(s) of previous site visits:

A. STUDY STATUS	**CURRENT VISIT**	**PREVIOUS VISIT**
1. Subject:		
No. Planned		
No. Screened		
No. Enrolled / Randomized		
No. on Test Article		
No. in Follow-up		
No. Withdrawn		
No. Completed		
2. No. Subject Records verified		
No. Informed Consents verified		
No. Entry Criteria Reviews completed		
3. No. SAEs (Reported since previous monitoring visit)		
4. No. Deaths (cumulative)		

Were all SAEs (reported since previous monitoring visit) reported to DMID?	☐ Yes	☐ No
Were all SAEs (reported since previous monitoring visit) reported to the IRB, if appropriate?	☐ Yes	☐ No

B. SUBJECT RECORD REVIEW SUMMARY	
PROBLEMS NOTED*	
1. Informed Consent Violations	
2. Enrollment Violations	
3. Protocol Violations	

* For Record Review Summary, problems are tabulated a maximum of once per category/per subject record. Refer to Protocol-Specific Report attachment for details on actual frequency and types of problems noted per category/subject/protocol.

C. ENROLLMENT / PROTOCOL VIOLATIONS		
Any enrollment / protocol violations noted this visit or since previous visit?	☐ Yes	☐ No
If yes, were all reported to DMID?	☐ Yes	☐ No
Were all violations reported to the IRB?	☐ Yes	☐ No

DMID CLINICAL TRIAL MONITORING REPORT

STUDY INTERIM VISIT

VISIT DATE (S)		**ISSUE DATE**	
STUDY SITE			
PI NAME			
CLINICAL SITE MONITOR			
CLINICAL TRIAL			
IND #		**DMID PROTOCOL #**	

I. SITE PERSONNEL			
TITLE	**NAME**	**MET WITH MONITOR?**	
Principal Investigator		☐ Yes	☐ No
Sub-Investigator (s)		☐ Yes	☐ No
		☐ Yes	☐ No
Study Coordinator		☐ Yes	☐ No
Research Clinician(s)		☐ Yes	☐ No
		☐ Yes	☐ No

OTHER SITE VISIT PARTICIPANTS	☐ Yes	☐ No
Comments:		

CHANGES IN PERSONNEL SINCE LAST VISIT	☐ Yes	☐ No
Comments:		

II. SITE VISIT ACTIVITIES				
REGULATORY AUDIT	☐ Yes	☐ No	☐ Comments	☐ Attachments
TEST ARTICLE ACCOUNTABILITY	☐ Yes	☐ No	☐ Comments	☐ Attachments
PROTOCOL-SPECIFIC REPORT	☐ Yes	☐ No	☐ Comments	☐ Attachments
LABORATORY VISIT	☐ Yes	☐ No	☐ Comments	☐ Attachments
CLINIC OPERATIONS VISIT	☐ Yes	☐ No	☐ Comments	☐ Attachments
STUDY CLOSE OUT VISIT	☐ Yes	☐ No	☐ Comments	☐ Attachments
Comments:				

III. PREVIOUS CLINICAL SITE MONITORING FOR THIS PROTOCOL		
DATE(S) OF VISIT	# OF SUBJECT RECORDS REVIEWED	SITE VISIT ACTIVITIES ACCOMPLISHED (list)

IV. SUBJECT RECORD REVIEW PROBLEM RESOLUTION ASSESSMENT	☐ Yes	☐ No	☐ Comments
Were problems from a previous site visit reassessed? Comments on problem resolution:			

*The monitor assesses whether certain previously identified problems have been resolved. These include subject-specific informed consent issues, or inadequate source documentation involving entry criteria or critical events.

V. REGULATORY ISSUES IDENTIFIED AT PREVIOUS VISIT	☐ Yes	☐ No
Regulatory Issues: If yes, briefly comment on issues identified in DMID follow-up letter to PI & issues identified by regulatory contractor (McKesson):		
Other Issues:		

VI. SITE TRAINING ACTIVITIES COMPLETED BY MONITOR	☐ Yes	☐ No
Comments:		

VII. DISCUSSION OF CURRENT FINDINGS WITH STAFF	☐ Yes	☐ No
Comments:		

VIII. DOES THE SITE HAVE A QUALITY MANAGEMENT PLAN?	☐ Yes	☐ No
If yes, date of plan:		
Is this protocol incorporated into plan? If yes, comment:		

IX. CRITICAL OBSERVATIONS AND RECOMMENDATIONS	☐ Yes	☐ No
Comments:		

X. PROBLEMS/NEEDS IDENTIFIED BY SITE	☐ Yes	☐ No
Comments:		

DMID CLINICAL TRIAL MONITORING REPORT
AUDIT OF REGULATORY FILE

VISIT DATE (S)		**ISSUE DATE**	
STUDY SITE			
PI NAME			
CLINICAL SITE MONITOR			
CLINICAL TRIAL			
IND #		**DMID PROTOCOL #**	

1. Study Notebook / File	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

2. Signed 1572	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Include date(s) & name of PI: Comments:				

3. Initial IRB Approval of Protocol and Consent(s)	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Original Date: Comments:				

4. Copy of Protocol(s)	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
If yes, date: Comments [Include IRB approval date(s)]:				

5. Copy of Amendment(s)	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
If yes, date: Comments [Include IRB approval date(s)]:				

6. Copy of Consent(s)	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up

If yes, date(s) & version including IRB approval:
Comments:

7. Annual IRB Reviews / Renewals	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
If yes, date(s): Comments:				

8. SAE Report Forms (since previous monitoring visit)	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
List subject No., date of event, diagnosis & whether or not submitted to Sponsor and IRB (if applicable):				

9. Safety Reports	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments (include when submitted to IRB):				

10. Copy of IRB approved Ads	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments (include date of ad & IRB approval date):				

11. MPA / SPA	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
If yes, Assurance number: Comments:				

12. Copies of blank CRFs	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

13. Investigator Brochure	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Versions on File: Comments [include IRB submission and approval date(s)]:				

14. Study–Specific Investigator / Nurses' Procedure Manual	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

15. Study-Specific Lab Manual / specimen handling instructions	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

16. Lab Normals	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
If yes, date(s): Comments:				

17. Lab Certification(s)	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
If yes, date(s): Comments:				

18. CVs (Investigator & Sub-Investigator)	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

19. Study personnel signature / initial sheet	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments (should include all study personnel completing CRF):				

20. Ancillary personnel and responsibility list	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments (should include personnel not listed on 1572):				

21. Sponsor Correspondence File	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

23. Monitoring Reports Present	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

24. Monitoring Log	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

ADDITIONAL COMMENTS

DMID CLINICAL TRIAL MONITORING REPORT
TEST ARTICLE ACCOUNTABILITY

VISIT DATE (S)		**ISSUE DATE**	
STUDY SITE			
PI NAME			
CLINICAL SITE MONITOR			
CLINICAL TRIAL			
IND #		**DMID PROTOCOL #**	

Test Article name (list):

I. DOCUMENTS

1. Test Article Receipts	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments (include date of receipt, test article name, lot no., & amount received):				
2. Test Article Transfer	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments (include date of transfer, test article name, amount transferred & authorization):				
3. Unused Drug Disposition Records	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments (must be documented on accountability record, transfer form, or test article return form):				
4. Patient Assignment List	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				
5. Randomization assignment maintained	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				
6. Blinding maintained	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

II. ACCOUNTABLITY

1. Review the test article accountability logs from protocol initiation to the present and answer the following questions.

a) Compare inventory balance documented on test article accountability record with actual physical inventory. Is inventory accurate?	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				
b) All test article supplies accounted for?	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comment on amount received, used, remaining:				
c) Have discrepancies, dispensing errors and / or deviations been properly documented?	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				
d) Is there documentation of routine physical inventories?	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comment on inventory frequency; provide actual time span between inventories:				

- **STORAGE & HANDLING**

1. Indicate where test article dispensed from:	☐ N/A	☐ Requires Follow-up

Comments:				
2. Briefly describe the test article storage area, noting accessibility of test article supplies:			☐ N/A	☐ Requires Follow-up
Comments (i.e. access control, relation to storage of other pharmacy supplies & how the test article supplies are organized):				
3. Is test article maintained at recommended temperature?	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Indicate range: Comments:				
4. Daily log of refrigerator / freezer temps maintained?	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				
5. Refrigerator / freezer containing test article equipped with auxiliary power supply or back up alarm?	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments:				

6. Is cold chain maintained in shipment of test article?	☐ Yes	☐ No	☐ N/A	☐ Requires Follow-up
Comments: (How is cold chain maintained? Explain.)				

ADDITIONAL COMMENTS

DMID CLINICAL TRIAL MONITORING REPORT
PROTOCOL-SPECIFIC REPORT

VISIT DATE (S)		**ISSUE DATE**	
STUDY SITE			
PI NAME			
CLINICAL SITE MONITOR			
CLINICAL TRIAL			
IND #		**DMID PROTOCOL #**	

DATE 1ST PATIENT ENROLLED:

DATE OF IRB APPROVAL:

I. SUBJECT RECORDS REVIEWED				
SUBJECT NO.	From Wk/Mo/Vis	dd/mmm/yy	Thru Wk/Mo/Vis	dd/mmm/yy

II.	DETAILED SUMMARY OF FINDINGS BY PID			
A.	Informed Consent Violations	☐ Yes	☐ No	☐ Requires follow-up
Comments:				
B.	Enrollment Violations	☐ Yes	☐ No	☐ Requires follow-up
Comments:				
C.	Inadequate Source Documentation	☐ Yes	☐ No	☐ Requires follow-up
Comments:				
D.	Missed / Late SAE / AE Reporting	☐ Yes	☐ No	☐ Requires follow-up
Comments:				
E.	Missed Clinical Endpoints	☐ Yes	☐ No	☐ Requires follow-up
Comments:				
F.	Protocol Violations	☐ Yes	☐ No	☐ Requires follow-up
Comments:				
G.	Protocol Deviations	☐ Yes	☐ No	☐ Requires follow-up
Comments:				
H.	Implementation Issues	☐ Yes	☐ No	☐ Requires follow-up
Comments:				

ADDITIONAL COMMENTS

DMID CLINICAL TRIAL MONITORING REPORT

RESEARCH LABORATORY VISIT

VISIT DATE (S)		**ISSUE DATE**	
STUDY SITE			
PI NAME			
CLINICAL SITE MONITOR			
CLINICAL TRIAL			
IND #		**DMID PROTOCOL #**	

Name of laboratory:	

Name of contact for each laboratory listed:	

List protocol-related tests conducted by each laboratory:	

LABORATORY SAMPLES	**COMMENTS**
1. What samples are being collected?	
2. Who collects the samples and how were samples collected?	
3. How/when are samples transferred from the clinical site to the laboratory?	
4. Describe how/when the data is assembled and returned:	

5. All samples analyzed on site? If no, who / where / when:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
6. Shipping records available for inspection:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
7. Are samples logged in? Describe:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments

Have lab technician pull random assortment of samples based on subject reviews completed (should include all types of samples required by protocol) for Questions #8, #9 & #10.					
8. Were sample labels clear and legible? List Subject No., Visit No. / week and type sample verified:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
9. Were samples easily trackable?	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
10. Were the above-mentioned samples stored properly? **How/where:** Temp range:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
11. Daily log of refrigerator/freezer temps being maintained: Describe method:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
12. Dedicated Study storage area: If no, describe measures utilized to prevent co-mingling.	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
13. Does refrigerator/freezer have auxiliary power supply or back up alarm?	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
14. Laboratory is blinded:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
15. Laboratory study manual supplied:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
16. SOPs for daily running/maintenance of laboratory/equipment established:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments

ADDITIONAL COMMENTS

DMID CLINICAL TRIAL MONITORING REPORT

OBSERVATION OF CLINICAL OPERATIONS

VISIT DATE (S)		**ISSUE DATE**	
STUDY SITE			
PI NAME			
CLINICAL SITE MONITOR			
CLINICAL TRIAL			
IND #		**DMID PROTOCOL #**	

THE FOLLOWING CLINICAL ACTIVITIES WERE OBSERVED DURING THIS SITE VISIT:					
I. Screening and Enrolling Volunteers For the Study				☐ Yes	☐ No
Study Nurse: Subject No.(s):					
1. Inclusion/Exclusion criteria reviewed:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
2. IRB approved consent form:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
3. Adequate time given to subject / parent to review the protocol /ask questions:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
4. Study risks, alternatives, and compliance issues discussed with patient:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
5. Consent signed prior to screening labs are drawn:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
6. Consent process done in private:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
7. Observed consent process was not coercive or intimidating:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments

II. Administration of Test Article				☐ Yes	☐ No
Study Nurse: Subject No.(s):					
1. Informed consent obtained before administration/distribution of test article:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
2. Test article preparation observed and followed per protocol:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
3. Test article administered as per protocol requirements:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
4. Procedures: Reactogenicity / Progress assessment:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments

III. Obtaining Laboratory Samples				☐ Yes	☐ No
Study Nurse: Subject No.(s):					
1. Type of sample:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
2. Where was sample obtained?	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
3. Sample was obtained by the method stated in the protocol/study manual:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
4. Adequate amount of sample was obtained:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
5. Sample was handled and transported to the laboratory by the prescribed means:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments
6. Samples were adequately labeled:	☐ Yes	☐ No	☐ N/A	☐ Requires follow-up	☐ Comments

ADDITIONAL COMMENTS

DMID CLINICAL TRIAL MONITORING REPORT
STUDY CLOSE OUT VISIT

VISIT DATE (S)		**ISSUE DATE**	
STUDY SITE			
PI NAME			
CLINICAL SITE MONITOR			
CLINICAL TRIAL			
IND #		**DMID PROTOCOL #**	

1. IRB(s) notified in writing of study completion / withdrawal	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

2. Final Report Submitted to the IRB	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

3. Final Report Submitted to the Sponsor	☐ Yes	☐ No	☐ Requires Follow-up
If no, when: Comments:			

4. Test article counted and final accountability assessed	☐ Yes	☐ No	☐ Requires Follow-up
List remaining test article (include both used and unused); Comments:			

5. Disposition of other remaining clinical / study supplies as per protocol	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

6. Copies of test article shipping, receiving, and accountability records collected?	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

7. Investigator reminded of responsibility of storing study file and confidential information	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

8. Disposition of CRFs discussed (brief description of instructions given to investigator and plans for storage, shipping to DMID, etc.)	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

9. Record contact person, address and phone number	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

10. Are laboratory samples being stored for future use?	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

11. Are laboratory samples being stored anonymously ?	☐ Yes	☐ No	☐ Requires Follow-up
Comments (Indicate):			

12. Does consent state that laboratory samples will be stored?	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

13. Does consent state for what purpose?	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

14. Has investigator identified a purpose?	☐ Yes	☐ No	☐ Requires Follow-up
Comments:			

ADDITIONAL COMMENTS (progress of phase-out to date)

VERSION DECEMBER 20, 2002: Additional Questions 20-30 to RFP-NIAID-NIH-DMID-03-33:

Question 20:
Reference: P.3, RFP
Please clarify bio-defense considerations which should be addressed in the proposal. For example, will it be important to address a higher level of security in processing classified information and in planning for safety reporting.

Answer 20:
The clinical trial data do not comprise classified information. Usual consideration of privacy issues and confidentiality of personally identifiable information pertains.

Question 21:
Reference: SOW E.4
Please clarify the role of the Call Center such as hours of required operation.

Answer 2l:

The toll-free telephone number (e.g., "call center") and website to provide information to the public about DMID–sponsored trials should be available 24 hours a day, seven days a week. At a minimum, responses to specific questions should be provided within a period of 12 hours for weekday queries and 24 hours for queries made on weekends and holidays. Offerors are encouraged to propose an efficient and cost effective approach to meet the government's requirement stated in the SOW.

Question 22: Reference: RFP L.2.d sections 7, 8, and 9
Ask for various sample SOPs, templates, QA Plan and a complete set of monitoring SOPs. Compliance with this requirement will require approximately 200 pages of documentation to be submitted as appendices or attachments. Will DMID grant an exception to the 150 page proposal limit for these documents or accept summary versions in lieu of actual SOP's?

Answer 22:
See response to #29 below.

Question 23:

Reference: RFP L.2.d.11. Information Management Systems
Please clarify/expand upon the requirement for "... predicted upper limits for time duration of the steps needed to accomplish the data management activities ..."

Answer 23: RFP Item L.2.d.11., Information Management System, is hereby revised to read as follows:
Offerors must describe in detail the various components of the proposed data systems and how they will function with respect to DMID and its clinical sites. The description should include a schedule, including steps and time frames, to accomplish the data management activities described in the Statement of Work.

Question 24:
Reference: SOW, Section D.12
Please provide additional detail on D12. For example, will Contractor be required to

transfer existing paper records to the new system of centralized data collection? How many unique trials will be involved? In what format does the paper information reside (CIOMSI, MedWatch, source documentation)?

Answer 24:
Yes, the contractor will be required to transfer existing paper records to the new system of centralized data collection – see SOW, item D. Data for all on-going DMID sponsored trials (~130 trials, see RFP page 3) will need to be transferred, along with data from a portion of completed trials that will be specifically identified by DMID (approximately 20 trials). As described in Item D.12 of the SOW, the current system is a paper system comprising source documentation.

Question 25: Reference: SOW D.9
Will Contractor handle Alert letter and/or reporting of like events to the investigative sites for IRB submission?

Question 26:
Reference: SOW D.9
Will Contractor provide reporting to manufacturers for Co-Suspect medications implicated in the safety reports?

Answer 25 and 26: DMID usually conducts clinical trials with investigational products under a Clinical Trials Agreement (CTA) with the manufacturer of the product. Under the terms of the CTA, safety data are provided to the manufacturer who is responsible for providing the related SAE data to other parties evaluating the investigational agent. DMID Regulatory Affairs reports all related SAE data to the FDA when DMID serves as IND sponsor. In addition, DMID reports all related SAE's to all DMID investigators evaluating the investigational agent, and it is the responsibility of the investigators to report these related SAEs to their IRBs. The contractor will have a limited role in transmitting related SAE reports to DMID investigators involved in any particular trial.

Question 27:

Reference: SOW D.12
Please provide additional details on the process flow for the DMID request. Will all Safety reports be submitted directly to DMID and then forwarded to Covance for Database entry OR will Safety reports be submitted to the Covance Regional Safety Centers, processed and submitted to DMID?

Answer 27:
As stated in Item D., first paragraph, the contractor is expected to "design, develop, implement and maintain a global Adverse Event/Serious Adverse Event (AE/SAE) reporting system that will constitute DMID's Pharmacovigilance Program". It is essential that DMID Medical Monitors are simultaneously apprised of SAE reports. Therefore, offerors should propose the most effective and efficient method.

Question 28: Reference: SOW F.1
States that "The Contractor shall be responsible for assessing the legacy data and transferring relevant information to the new database."

What types of legacy data are involved (e.g. paper, like in SOW D.12, data on legacy databases that requires migration, etc.), what is the anticipated volume of legacy data to be transferred and over what timeline?

Answer 28:

As stated in the SOW and reiterated in Amendment #1, Question/Answer #10, data are dispersed across several locations and is maintained in various forms, including paper and electronic files (e.g., MS Word, MS Excel). It is anticipated that relevant data from all on-going trials and from a small number of DMID-designated completed trials (see answer to question #5, above, for estimates) will be transferred to the new databases identified in the SOW within the first year of the contract.

Question 29:

The Amendment #1 has excluded ONLY the CRFs and the monitoring SOPs from the 150 page limit. Per page 58 of the RFP, the offeror must include samples of protocols for a Phase I vaccine and a Phase I drug study. Please clarify if these sample protocols are also excluded from the 150 page limit.

ANSWER 29: In addition to the page limitation exclusions noted in Amendment 1, samples of standardized protocol templates Phase 1 vaccine and Phase 1 drug studies are excluded from the 150 page limit.

Question 30:

Will the contractor be required to repackage and/or label study drug? If so, please specify the repackaging and/or labeling requirements.

Answer 30:
In some instances this may be the case. If so, repackaging and/or labeling of test articles should be conducted in accordance with applicable guidance and regulations. Refer to the Statement of Work, Item B.9, Product/Agent Distribution (page 7) for additional information.

END OF MODIFICATION #1 TO RFP NIH-NIAID-DMID-03-33

- Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.
- The hour and date specified for receipt of offers REMAINS: January 7, 2003, **2002, 4:00 PM, EST**.
- Offerors must acknowledge receipt of this Amendment #1, on each copy of the proposal submitted.

Failure to receive your acknowledgement of this amendment may result in the rejection of your offer.

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